



# Lab-Oratory

North Carolina  
N.C. Department of Health and Human Services / State Laboratory of Public Health

## INSIDE this issue

### PAGE 2

Cystic Fibrosis to be added to Newborn Screening Panel

### PAGE 3

Annual Meeting of the State Board of Health  
June, 1908

### PAGE 4

4<sup>th</sup> Annual Clinical Laboratory Day

### PAGE 5

Local CMLA Chapter Revitalized

### PAGE 6

Lab Test of the Quarter

### PAGE 7

Schistosomiasis

### PAGE 8 / EDITORIAL

Needle Points

*Happy Birthday to You!*

### PAGE 9

Access to On-line Study Delayed

### PAGE 10

Microscopy Notes

### PAGE 12

State Laboratory Begins Testing for HPV

### PAGE 13

New State Laboratory web site

**MORE...** QA Tips on p.9,  
The Safety Corner on p.14, and  
"Dear Lab-bey" on p.11

Lab-Oratory, September 2008

Number 92

## From the Director's Chair

October is one of my favorite months in North Carolina. As the summer winds down and we look forward to fall, I thought it would be a good time to reflect on the last legislative session, as well as the current status of two large projects involving the N.C. State Laboratory of Public Health.

### General Assembly Update

The last legislative session was largely successful for the NCSLPH. We received funding approval for reallocation of four key positions: the Assistant Public Health Laboratory Director, a dedicated Laboratory Safety Officer, a Medical Laboratory Supervisor II position to oversee a molecular diagnostic/molecular epidemiology group, and a Medical Laboratory Technologist II position to round out this new molecular group. It will be exciting to recruit and eventually hire these much needed roles. Another success was approval to add screening for Cystic Fibrosis to our newborn screening panel. The NCSLPH will perform an initial biochemical test on every baby, followed by a DNA test on a smaller percentage of newborns for confirmation of certain mutations present in our population. In order to implement this testing, three new positions were approved: a Laboratory Improvement Consultant dedicated to the newborn screening program, a Medical Laboratory Specialist to perform DNA testing, and a Medical Laboratory Technologist II to perform the biochemical testing.

Cont. on page 2



Leslie A. Wolf, PhD, HCLD (ABB)  
Laboratory Director

## MISSION statement

*The State Laboratory of Public Health provides certain medical and environmental laboratory services (testing, consultation and training) to public and private health provider organizations responsible for the promotion, protection and assurance of the health of North Carolina citizens.*

Director's Chair cont. from page 1

### **STARLIMS Update**

The NCSLPH is entering the final stages of completing the STARLIMS project. Many of our clinical and environmental laboratories are poised to go into either parallel testing with the current LIMS or to go into production. It is critical that we maintain and expand the reporting of laboratory results on our website, as well as to transfer data to our partners in an automated fashion. To this end, we have worked with our NCEDSS partners closely to ensure that reportable laboratory information is transferred to NCEDSS to meet the electronic laboratory reporting (ELR) requirement.

### **New Facility Update**

The NCSLPH and the Office of the Chief Medical Examiner continue to work with the design team in the construction/design phase of the project. The steering committee for the new facility decided early on that the exterior and the interior should reflect the colors of the site, and thus should include earthy tones such as browns, reds, greens, oranges and yellows. The exterior materials have been chosen to complement the site, and will be a combination of brick, metal and glass. The interior fabrics, flooring and color palette will be combinations of earthy colors that help identify zones within the building. The targeted date for completion is December 2010, with move-in occurring in January 2011.

*Dr. Leslie Wolf, Lab Director*

---

## **Newborn Screening Panel to Include Cystic Fibrosis**

Babies born in North Carolina will soon be screened for cystic fibrosis (CF) when their newborn screening specimens are submitted to the North Carolina State Laboratory of Public Health. The addition of this common genetic disorder to the current panel of tests was recently approved by the state legislature. It is anticipated that CF newborn screening can be implemented by early 2009.

CF is the most common genetic disease in the Caucasian population, with an incidence of 1 in 2,500 live births. The disease also occurs in 1 in 6,000 Hispanic, 1 in 10,000 African-American and 1 in 90,000 Asian-American births. Eighty-five percent of CF patients do not present with clinical symptoms at birth, and without newborn screening most are not diagnosed until after 1 year of age.

CF results from mutations in the gene that regulates chloride transport through various membranes in the body. The disorder is autosomal recessive, meaning that a defective gene must be inherited from each

parent for the disease to be present. The abnormal transport of chloride causes the most serious complications in the lungs, where dehydrated mucous becomes thick and sticky. Microorganisms and debris are unable to be cleared by the cilia, causing airway obstruction and infections. Permanent damage to the lungs is often a result of the recurrent infections. Over 90 percent of CF patients die from lung involvement.

A second effect of CF occurs when the pancreas becomes obstructed by thick mucous and is unable to secrete the enzymes necessary to help the body break down and absorb food. This results in poor growth, weight loss, abdominal pain and frequent, greasy, bulky stools. These symptoms are greatly improved with replacement of pancreatic enzymes and careful diet planning.

Other clinical manifestations of CF may include male infertility, liver disease, bowel obstruction, recurring sinusitis and nasal polyps. Approximately 15-20 percent of CF-affected newborns present with meconium ileus. Meconium is the term used to refer to the earliest stools of the infant after birth. Composed of materials ingested by the infant while in the uterus, these stools are viscous, sticky and odorless. Meconium is normally passed by the first few days of postpartum life, progressing to the yellowish stools of digested milk. In infants with CF, the meconium becomes thickened and causes an obstruction in the ileum or final section of the small intestine; hence the term "meconium ileus."

**Cont. on page 3**

## Newborn Screening Panel cont. from page 2

Newborn screening for CF allows for early diagnosis and therapy intervention. Studies have shown that patients diagnosed soon after birth have improved nutritional status and growth, improved lung function and fewer hospital stays, resulting in longer, healthier lives. In 1955, children with CF were not expected to live beyond age 6. Today, individuals with this disease are living into their thirties and forties and have lives that include careers, marriage and families of their own.

North Carolina joins a growing number of states currently screening newborns for CF in an effort to improve the quality and quantity of life for affected individuals. Testing for this disorder will not require any additional specimen collection, as the filter portion of the current newborn screening form allows for adequate sample. Primary screening for CF will be performed by quantitating the amount of immunoreactive trypsinogen (IRT) present in the blood sample. IRT is a pancreatic protein typically elevated in CF-affected infants, with a high level indicating the need for a second tier of testing. DNA analysis will be used as the second tier and will detect gene mutations associated with the disease. Depending on the outcome of the DNA analysis, infants may be referred to a CF care center for sweat testing, which is the gold standard for diagnosis of CF.

The State Lab will work closely with follow-up personnel to ensure all babies needing further evaluation are seen by CF specialists. The combination of newborn screening, genetic counseling for families of affected individuals and an early treatment plan can greatly improve the lives of patients with this disorder. More information will follow as the lab nears implementation of CF newborn screening.

## References:

1. Kleven DT, McCudden CR, Willis, MS. Cystic fibrosis: newborn screening in America. *Medical Laboratory Observer*, July 2008, 16-27.
2. Comeau AM, Accurso FJ, et al. Guidelines for Implementation of Cystic Fibrosis Newborn Screening Programs: Cystic Fibrosis Foundation Workshop Report. *Pediatrics*, vol 119, no 2, Feb 2007, 495-518.

*Submitted by:*

*Patty Atwood, MT (ASCP)*

*North Carolina State Laboratory  
of Public Health*

## N.C. Public Health, 100 years ago...

### Annual Meeting of the State Board of Health

June, 1908

"...The chief and most important work of the year has been the reorganization and refitting of the State Laboratory of Hygiene, which while a separate entity, is placed by the law under the control of the State Board of Health. Upon the retirement of Dr. McCarthy, we were fortunate in securing as director of the laboratory, a man well educated academically and well trained technically, an MS of our own

University and an MD of Johns Hopkins, with a biological laboratory experience of nearly ten years—Dr. C. A. Shore, who, by the way, is a citizen of this goodly town. We have been likewise not less fortunate in securing as chemist Miss Daisy B. Allen, who, I am assured by Dr. Herty, professor of chemistry at the University, has never been excelled, if equaled, by any graduate of that department during

his incumbency. Thanks to the generosity of the Legislature, we were enabled to thoroughly refit the laboratory with the most approved apparatus, and first-class work can be expected...."

*Excerpt from the Bulletin  
of the North Carolina Board of Health  
Vol. XXIII, No. 3.*

## 4<sup>th</sup> Annual Clinical Laboratory Day: *Ride the "Waive" of Laboratory Testing*

A great learning opportunity, *Ride the "Waive" of Laboratory Testing* was held Aug. 8 in Raleigh. The Laboratory Improvement section of the North Carolina State Laboratory of Public Health (NCSLPH) partnered with the Texas Health Institute to deliver this educational conference, which boasted talented speakers with many years of experience and knowledge. Over 100 people attended the conference from all across the state of North Carolina. Vendors who generously provided funding for the conference included American MicroOptics Inc., Fisher Scientific, HemoCue Inc., Lab Supply Company, Olympus, and the North Carolina Public Health Association Laboratory Section.

The event was held on the campus of Wake Technical Community College. The President of Wake Tech, Dr. Stephen Scott, opened the conference with a friendly greeting and a few words about the college. The director of the NCSLPH, Dr. Leslie Wolf, followed with a warm welcome to the speakers, participants and vendors. She expressed how important good lab practice and quality assurance are in the laboratory.

The first speaker was Sharon Cibrik, MT(ASCP) NCA(CLS). Sharon is the Microbiologist Supervisor for the West Virginia Office of Laboratory Services. She is also the State Training Coordinator and supervises the operation of the CLIA office in West Virginia. Her extensive knowledge comes from working at various hospitals and the West Virginia State Lab for over 30 years. In her informative presentation, she discussed how CLIA regulations relate to laboratory test menus and defined good lab practices to put into use. Many participants commented they would bring information back to their coworkers and ensure their facility was CLIA compliant.

The next speaker was C. Anne Pontius, MBA, CMPE, MT(ASCP). Anne was previously the Senior Director of Quality Systems at Expression Analysis, Inc. Anne's thorough knowledge and experience was a great asset to our program. She discussed how to implement a Quality Assessment program, defined a Quality Management System, and covered all of the components of a good system. The participants took home extremely valuable information.



*Anne Pontius explained the implementation of a Quality Management system.*



*Tim Dumas describes how to keep a positive attitude in the workplace through humorous stories and magic tricks!*

After a fabulous lunch provided by the Dakota Grill, the participants were able to join in a guided discussion panel, a new feature for Clinical Lab Day this year. Five experts agreed to sit on the panel and answer questions from the audience. Dr. Ed Geddie joined us from N.C. Department of Labor to answer safety-related questions. Dr. Leslie Wolf answered questions regarding the NCSLPH, and Sharon Cibrik stayed on to answer more CLIA-related questions. Kristy Osterhout from the NCSLPH shared her knowledge of packaging and shipping regulations. To

complete the panel, Georgena Millar utilized her 30 years of experience to discuss questions regarding the NC CLIA contract. Questions were collected in advance from local health departments, and Sherri Felts posed the questions to each panelist. Many helpful answers were revealed.

Cont. on page 5

4<sup>th</sup> Annual Clinical Laboratory Day cont. from page 4

The final speaker was a special treat. Tim Dumas, MLT wrapped up the conference with a presentation entitled, "Quality Control for Your Attitude." Tim explained how humor and positive attitude can create people who are happy and enjoy the work that they do. Through funny stories and magic tricks, Tim captured the audience's attention and demonstrated how to keep a positive attitude. The participants responded with laughter and the day was concluded in a great fashion. Everyone went home with smiles on their faces!



*Vendors interact with the participants at the 4<sup>th</sup> Annual Clinical Laboratory Day.*

The Lab Improvement staff was thrilled to provide such an educational opportunity to laboratorians across the state of North Carolina. The overall experience of the speakers was astounding and was evident through their excellent presentations. Many participants appreciated the content on CLIA and Quality Assurance, as it is of utmost importance in their jobs. The "Quality Control for your Attitude" was an added bonus and encouraged the participants to keep a more positive attitude in the workplace. The partnership between N.C. State Laboratory of Public Health and Texas Health Institute proved successful and provided a well-received conference.

*Submitted by:*

*Kristy Breedlove, BS*

*Laboratory Improvement Consultant*

*North Carolina State Laboratory of Public Health*

## Local CLMA Chapter Revitalized

In January 2008, the Eastern NC Chapter of CLMA changed its name to Heart of North Carolina Chapter of CLMA. With this new name came new faces, new energy and fresh ideas.

For those not familiar with the Clinical Laboratory Management Association (CLMA), membership has a lot to offer. Founded in 1976, CLMA is an international association of 5300 clinical laboratory professionals, with a mission of empowering laboratory professionals to achieve excellence in leadership. This is accomplished through forward-thinking educational, networking, and advocacy opportunities.

By joining CLMA, you will have access to:

- Networking opportunities with laboratory professionals from all levels and settings.
- Opportunities to earn CE close to work or home at our local chapter meetings.
- Full access to MasterMind: CLMA's Knowledge Center.
- Subscriptions to all CLMA publications.
- Legislative and regulatory updates.
- Eligibility for member pricing for the CLMA ThinkLab Conference & Exhibition.

To learn more about CLMA, visit [www.clma.org](http://www.clma.org).

Please do not hesitate to contact me with any questions about CLMA's benefits and membership. I hope to see you soon at the next *Heart of North Carolina Chapter of CLMA* event!

*Submitted by:*

*Lisa O. Ballance, BSMT(ASCP), CLC(AMT)*

*Board Member, HNCC, CLMA*

*[Lisa.ballance@ncmail.net](mailto:Lisa.ballance@ncmail.net)*

# Lab Test of the Quarter

## Serum Electrolytes (Part 4 of 4)

**Carbon Dioxide** (a.k.a. CO<sub>2</sub> content, CO<sub>2</sub> combining power, bicarbonate, total CO<sub>2</sub>, TCO<sub>2</sub>): “The amount of carbon dioxide that the blood serum can hold in chemical combination. CO<sub>2</sub> in aqueous solution forms carbonic acid; the amount of this acid that blood serum can take up is a measure of its reserve power to prevent acidosis.”

-Taber's Cyclopedic Medical Dictionary

### CO<sub>2</sub> Normal Ranges (serum/plasma)

#### Adult/Elderly:

23-30 mEq/L

#### Child:

20-28 mEq/L

#### Infant:

20-28 mEq/L

#### Newborn:

13-22 mEq/L

#### Critical Values:

<6 mEq/L

- Mosby's Diagnostic and Laboratory Test Reference.

The CO<sub>2</sub> test, not to be confused with the partial pressure of CO<sub>2</sub> (PCO<sub>2</sub>), is a measure of carbon dioxide in blood (serum or plasma) and is usually run in conjunction with the other serum electrolytes, sodium, potassium, and chloride routinely (i.e., during an annual physical) or if the patient is experiencing the following symptoms: weakness, confusion, prolonged vomiting, respiratory distress, or losing/retaining fluid. These symptoms could indicate an electrolyte or acid-base imbalance. This test measures the following: H<sub>2</sub>CO<sub>3</sub> (carbonic acid), dissolved CO<sub>2</sub>, and HCO<sub>3</sub><sup>-</sup> (bicarbonate ion) and will give a rough estimate of the body's bicarbonate ion.

### Abnormal Findings (Increased CO<sub>2</sub> Levels)

• Cushing syndrome	• Metabolic alkalosis
• Breathing disorders	• Gastric suction
• Severe diarrhea	• Medications such as Aldosterone, barbiturates, bicarbonates, ethacrynic acid, hydrocortisone, loop diuretics, mercurial diuretics, and steroids.
• Starvation	
• Severe vomiting	
• Hyperaldosteronism	
• Emphysema	

### Abnormal Findings (Decreased CO<sub>2</sub> Levels)

• Addison disease	• Shock
• Ethylene glycol poisoning	• Starvation
• Methanol poisoning	• Under-filling the tube, which causes CO <sub>2</sub> to escape from the specimen
• Renal failure	
• Salicylate toxicity	
• Diabetic ketoacidosis	• Medications such as methicillin, nitrofurantoin, paraldehyde, phenformin, hydrochloride, tetracycline, thiazide diuretics, and triamterene.
• Lactic acidosis	
• Metabolic acidosis	

Bicarbonate works in a similar manner as chloride (both negatively charged) to maintain a neutral pH in intracellular and extracellular body fluids, which is essential to life.

#### References:

Carbon Dioxide Combining Power. Taber's Cyclopedic Medical Dictionary: 18th Edition. Ed. Clayton L. Thomas. Philadelphia: F.A. Davis Company, 1997.

CO<sub>2</sub>. Lab Tests Online. 2005. Available at <http://www.labtestsonline.org/understanding/analytes/co2/glance.html>. Accessed August 19, 2008.

Van Voorhees BW. CO<sub>2</sub> Test: Serum. Medline Plus Medical Encyclopedia. 2007. Available at <http://www.nlm.nih.gov/medlineplus/ency/article/003469.htm>. Accessed August 19, 2008.

Pagana, KD, Pagana, TJ. Carbon Dioxide Content. Mosby's Diagnostic and Laboratory Test Reference: 4th Edition. St. Louis: Mosby, 1999.

#### Submitted by:

Jennifer Anderson, BS, MT(ASCP)<sup>CM</sup>  
Laboratory Improvement Consultant

# Schistosomiasis

Schistosomiasis, also known as bilharzia, is caused by parasitic worms. It is the second most prevalent tropical disease in the world, behind malaria. It is endemic in over 75 countries; however, as a result of industrialization and the tourism industry, schistosomiasis can present anywhere in the world. Geographic distribution of infection is determined by the presence of the intermediate host snail. Schistosomiasis most heavily affects developing countries in Africa, South America, the Middle East and Asia.

*Schistosoma* species have a rather complex life cycle involving a human host and an intermediate snail host. Cercariae develop in the snail and later attach to human hosts using oral and ventral suckers. They migrate through intact skin to dermal veins and on to the pulmonary vasculature. During this migration, they develop to schistosomula and start involving major histocompatibility complexes and blood group antigens. From here, they migrate to the systemic circulation, which carries them to portal veins where they mature. Once adults, the males and females pair off and migrate to the mesenteric or vesicular veins (depending on the species), where they begin to produce eggs. These eggs migrate through the bowel or bladder wall where they mature into miracidia to be shed in the feces or urine. The free-swimming miracidia that are shed into freshwater can survive two to three weeks while they look for a susceptible snail to complete their cycle. Sporocysts multiply inside the snail and develop into cercariae. The free-swimming cercariae exit the snail and can survive for about 48 hours while they try to find a new human host, and the cycle continues. Human hosts can become infected when they come in contact with fresh water

contaminated with urine or feces from an infected host. They cannot become infected with schistosomiasis by swimming in salt water or chlorinated swimming pools. All humans are equally susceptible if exposed.

*Schistosoma mansoni*, *haematobium*, and *japonicum*, all cause illness in humans. Less prevalent species such as *Schistosoma mekongi* and *intercalatum* may also cause disease. Symptoms of schistosomiasis depend on the number and location of the eggs in the host system. Initially, there may be a general ill feeling, followed within a few hours by rash or itchy skin. More serious symptoms, if present, usually do not occur until four to six weeks after infection. Acute illness (Katayama fever) is characterized by fever, cough, abdominal pain, nausea, loss of appetite, weight loss, diarrhea, hematuria, headache, and joint and muscle pain. If the central nervous system is involved (i.e., mass lesions of the brain or spinal cord), seizures or transverse myelitis may also occur.

Severity of schistosomiasis is determined by the number of worms and the length of time a person has been infected. If the infection is treated early and severe end-organ complications have not occurred, prognosis is very good, and full recovery is expected. However, if left untreated, serious complications or death may occur. Prognosis is also poor in the case of co-infection with diseases like malaria, HIV, or hepatitis.

The World Health Organization estimates that of 600 million people at risk for infection worldwide, 200 million are already infected. Approximately 85 percent of these live in sub-Saharan Africa. Cases that occur in the United States are imported, as the snail that

serves as the intermediate host for the infection is not endemic in this country. North Carolina has had a steady increase in the number of cases verified at the State Lab. From 2000 to 2005, the only positive sample had been a proficiency sample received from the College of American Pathologists. In 2006, there were three positive samples, all of which came from the same patient, a refugee. In 2007, there were nine positive samples, three each on three patients, also refugees. As of June 2008, there have already been six positives this year, three each on two patients, both of these refugees as well. While these cases all presented in Wake County, the exact origin of the patients is unknown.

Prevention of infection lies in avoiding activities that can lead to infection. People should drink safe water, or boil water to kill harmful organisms. Bath water should be heated to 150°C for five minutes, although shower water kept in storage tanks for at least 48 hours is considered safe. Vigorous drying with towels after accidental exposure may reduce the risk of infection, but there is no guarantee. Improved sanitation systems and molluscicides, which decrease the prevalence of the snail hosts, are more drastic measures that can be taken to reduce the risks.

The World Health Organization's goal is to reduce severity of this disease rather than to completely halt its transmission. It is also planning to research a vaccine against the disease. At this time, there is no prophylaxis to protect against infection, and there is little immunity to protect against re-infection.

*Submitted by:*  
Crystal Poppler, BSCLS (ASCP)  
Laboratory Improvement

# EDITORIAL

## Needle Points

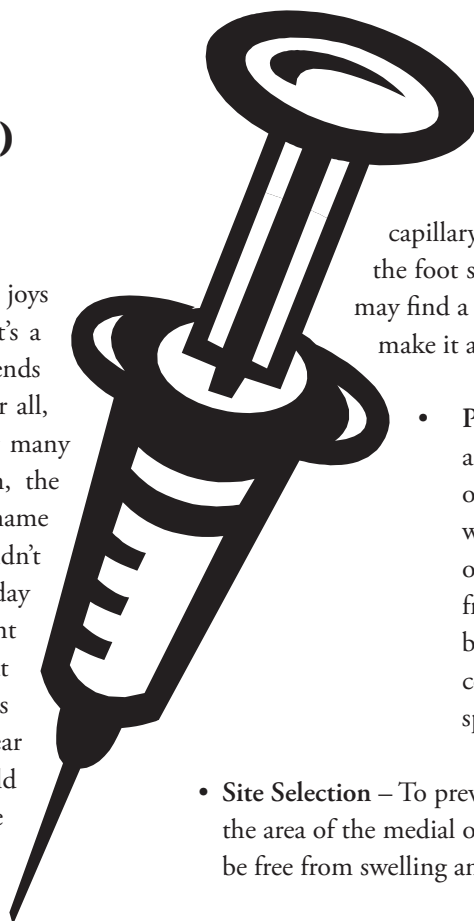
By Lisa O. Ballance,  
BSMT (ASCP), CLC (AMT)

### Happy Birthday to You!

For anyone who has experienced the joys of a baby's first birthday, you know it's a momentous occasion, celebrated by friends and family alike. And why not? After all, a baby's first year of life is marked by many important milestones—the first tooth, the first word, the first steps—just to name a few. But one thing a baby shouldn't experience before his/her first birthday is a fingerstick. Only when an infant is old enough to officially squish that first piece of birthday cake between his fingers, jam it into his mouth, and smear gobs of icing in the process, should this method of capillary collection be considered.

Those who perform blood specimen collection may be tempted to rush a baby's first-fingerstick milestone. Some base their decision on the weight of the baby, rather than age. Others use a baby's walking before his/her first birthday as justification for choosing the finger as the collection site. The problem with these approaches is that regardless of an infant's weight or ability to walk, there's no guarantee that the body fat will be proportionally distributed to the fleshy pads of the fingertips to safely support a puncture. To date, there are no published studies in existing literature to support either of these practices.

According to the Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS), punctures must not be performed on the fingers of a newborn or an infant less than one year old. That's because with this age group, there's a risk of bone penetration when



lancing little fingers. Such injury could result in complications, including infection and gangrene. For patients under 12 months of age, the lateral or medial plantar surfaces of either heel are the recommended sites for capillary puncture. The back of the heel and the arch of the foot should not be used. Some healthcare professionals may find a heelstick challenging, but a few procedure tips can make it a happier experience:

- **Positioning** – Proper positioning of the infant goes a long way toward a successful collection. In an outpatient setting, drawing an older, active baby while he/she is secured in an infant carrier is one option. Another is soliciting adequate assistance from either a parent or coworker. Keeping the baby's foot below the plane of the heart during the collection aids the filling of the capillary beds, speeding collection.
- **Site Selection** – To prevent tissue fluid contamination of the specimen, the area of the medial or lateral plantar surface of the heel selected should be free from swelling and previous puncture.
- **Prewarming** – Studies have shown that prewarming increases blood flow to the area up to sevenfold. A commercial heel warmer or warm compress not to exceed 42°C should be applied to the intended puncture site for 3-5 minutes. Investing time up front in prewarming will reduce the collection time overall, since the blood will flow more quickly, resulting in less squeezing and a better quality sample.
- **Equipment Selection** – In terms of lancets, there are two types of devices available. Puncture devices penetrate the skin vertically, whereas incision devices slice the tissue in a horizontal fashion. Studies indicate that for heelsticks, incision devices offer certain advantages over traditional puncture devices. These include 1) shorter collection times, because the blade cuts across more capillary beds, 2) less discomfort to the infant, and 3) faster healing of the incision. Regardless of the device selected, the depth of puncture should not exceed 2.0 mm.
- **Post-puncture Care** – Once the collection is complete, elevate the heel above the body and apply pressure to the site using a clean gauze pad until bleeding has stopped. Elevating the foot slows the flow of blood. Because of the choking hazard adhesive bandages pose, CLSI advises against their use on children less than two years of age.

Cont. on page 9

## Needle Points cont. from page 8

As every parent knows, babies don't stay babies for very long. As healthcare professionals charged with their care, we should recognize the importance of not rushing a blood collection method that could prove detrimental. By doing so, we help ensure that a baby's first year of life will be a happy one for all.

## Bibliography

1. NCCLS. Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard – Fifth Edition H4-A5. Wayne, PA: Clinical and Laboratory Standards Institute; 2004.

**Author's Note:** *Lisa Ballance is a Laboratory Improvement Regional Consultant based in Fayetteville, NC, and has served on working groups in the revision of CLSI's blood collection standards. Have a phlebotomy question? Email it to [lisa.ballance@ncmail.net](mailto:lisa.ballance@ncmail.net).*

# QA Tips

## June / July 2008 – QA Tip

### Who are our customers?

Most people will answer "the facility that sends us the samples". They certainly are one of our customers, but think about who some others may be:

1. The person who calls because they need information about our services
2. The lab manager in the local health department who notifies us about mis-directed mail
3. Staff from other programs who need our assistance, or
4. Staff in one unit in our lab who needs assistance from another unit.

A customer is anyone who needs information or services from our laboratory; customers can be people outside our facility or staff working together inside our laboratory. Good customer service is a quality indicator and lets our "customers" know more about us.

Reference: "Quality Qorner". LabMedicine, Volume 36. No. 5 May 2005.

## Access to On-line Study Delayed

The *Urine Microscopic Examination Study* has encountered technical problems with the State Lab web server. The interactive program features several video clips of urine elements and microorganisms. Unfortunately, the videos will not play in the on-line format. In an effort to make this training available as soon as possible, the State Lab is making the study available on a compact disc (CD). The

videos embedded in the study will run in the CD format on most computers.

Requests for the CD may be sent to [colleen.miller@ncmail.net](mailto:colleen.miller@ncmail.net) or call (919)807-8578.

*Submitted by  
Colleen Miller, BS MT(ASCP)  
Laboratory Improvement Consultant*

# Microscopy Notes

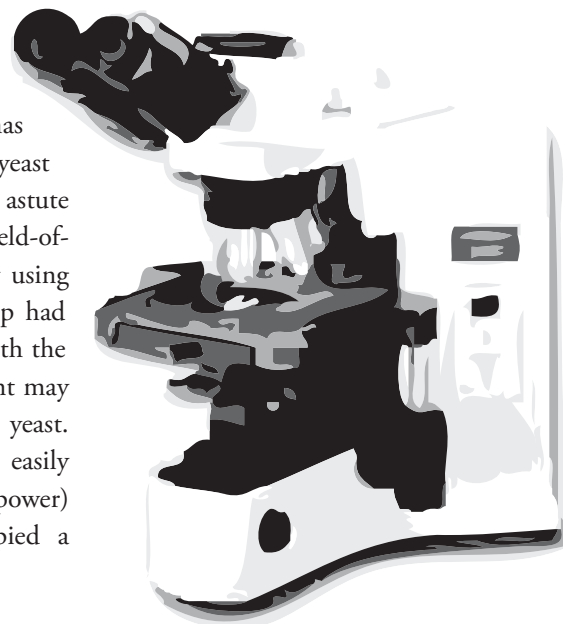
When selecting an objective lens for viewing, keep in mind that bigger is not always better. Many beginners in microscopy are generally obsessed with magnification and believe that the higher the magnification, the better. As most of us know, this is not true.

If you had the choice of only one objective, which would it be? If you chose the 10x (low power) objective, you made a wise decision. The 10x objective provides a greater depth-of-field (thickness of the specimen that can be clearly focused) and a larger viewing area (field-of-view) than objectives of higher magnifications. It is the most-used objective on the microscope and provides a final magnification of 100x when using a 10x ocular lens.

The 10x objective is used primarily for initially finding a specimen and then focusing on the subject. It is a scanning objective that allows the microscope user to review the specimen at a “distance”. Think of it in the context of the old phrase, “You can’t see the forest for the trees.” If a microscopist is overly concerned with details in a specimen, he or she may overlook the specimen as a

whole. For example, if a patient has a vaginal yeast infection with rare yeast cells and pseudohyphae, an astute microscopist will find that one field-of-view containing pseudohyphae by using the 10x objective. If the wet prep had not been scanned in its entirety with the low power objective, the wet mount may have been reported negative for yeast. The rare pseudohyphae is more easily overlooked with the 40x (high power) objective, as it may have occupied a field-of-view that was not studied.

A good depth-of-field is necessary, particularly when viewing wet mount examinations and urine sediments. As microorganisms and elements constantly move in and out of focus in the watery medium, the 10x objective allows the user to view more optical planes with better clarity. If an image detail is to be studied, a higher magnification will have to be used. Using the 40x objective will improve resolution; i.e., the ability of a microscope to reveal fine detail in a specimen. The 50x and 100x objectives provide even greater resolution, but are oil-immersion objectives and must be used with fixed slides unless using darkfield microscopy.



Learn more about the proper use and care of a microscope. The North Carolina State Laboratory of Public Health offers microscopy classes for beginner and advanced microscope users. Information about the classes may be found at <http://slph.ncpublichealth.com/labimprovement/labtraining.asp>.

*Submitted by  
Colleen Miller, BS MT(ASCP)  
Laboratory Improvement Consultant*

## EIN? What is it?

Many of the specimen submittal forms provided by the North Carolina State Laboratory of Public Health request an Employer Identification Number (EIN). Whether completing the Blood Lead Analysis form (#DHHS-3707) or Public Water Supply Analysis form (DHHS-2887), the EIN# is required. Also known as a Federal Tax Identification Number, the EIN is a nine-digit number that the Internal Revenue Service (IRS) uses to identify taxpayers who are required to file various business tax returns. These taxpayers include employers, sole proprietors, corporations, partnerships, non-profit organizations, trusts and estates, government agencies, certain individuals and other business entities. It is imperative that this number be provided by the agency submitting specimens for testing to the State Lab. The lab uses this number to log samples into the laboratory information management system. If you are unsure of your agency’s EIN#, contact your company’s business office.



## “Dear Lab-bey”

### What are my responsibilities as the shipper’s employer regarding training, recordkeeping and handling specimens?

An employer/shipper is required by law to comply with US transportation regulations for the safe transport of Category A infectious substances. A Category A infectious substance is in a form that is capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Penalties are imposed for non-compliance; up to \$500,000/violation. Penalties for training violations, the most common, are up to \$450/violation.

#### **Training:**

An employer must provide training for employees performing shipping duties:

- Provide or verify that
  1. Training is specific to current job function and
  2. Testing demonstrates a satisfactory knowledge of regulations to perform current job function.
- Certify that employee has been trained and tested.
  1. Certification means: mastery of materials
  2. Employee must pass a test to assure competency
  3. Training is required at least once every three years for DOT and at least once every two years for IATA and CAP accreditation
- Develop and retain current training records for each employee
  1. Inclusive of the preceding three years
  2. Retain throughout the entire length of employment and 90 days thereafter.

Formal certification training is not required if you never ship Category A specimens. However, you **MUST** know the regulations and you **MUST** know how to apply the regulations depending on whether you are shipping DOT, IATA or Private Carrier.

#### **Handling specimens:**

An employer must:

- Provide appropriate materials for shipping specimens
- Must be in contact with your carrier and assure that you are meeting their most recent rules.
- Provide appropriate safety training, security awareness and emergency response information
- Provide driver training
- Provide 24-hour emergency notification

Cont. on page 12

"Dear Lab-bey" cont. from page 11

### **Recordkeeping:**

#### **An employer must:**

- Retain one copy of each Shipper's Declaration of Dangerous Goods on file for 375 days
- Retain training records for the entire length of employment and 90 days thereafter.
- Ensure that the information on the Shipper's Declaration of Dangerous Goods is accurate, easy to identify, legible and durable;
- Ensure the Shipper's Declaration of Dangerous Goods is properly signed when the shipment is presented to the operator for shipment.

Please contact Kristy Osterhout at (919)733-7186 or [kristy.osterhout@ncmail.net](mailto:kristy.osterhout@ncmail.net) for all your packaging and shipping questions.

*Submitted by:*

*Kristy Osterhout, BS, SLS(ASCP)*

*Lab Improvement Coordinator*

---

## **State Laboratory Begins Testing for HPV**

Human papillomavirus (HPV), the causative agent of genital warts, is the most common sexually transmitted infection, affecting both men and women. According to the American Social Health Association, approximately 5.5 million new cases of sexually transmitted HPV are reported every year. In fact, at least 80% of women by the age of 50 will have been infected with genital HPV at some time in their lives.

Persistent HPV infection has been closely linked to cervical cancer in women, particularly infection with certain "high-risk" HPV genotypes including types 16 and 18. Traditional Pap smears and liquid-based cytology (ThinPrep®) look only for abnormal cervical cell changes. The State Laboratory of Public Health (SLPH) Cancer Cytology Unit received approximately 95,000 ThinPrep® samples in 2007; 5.7% were

reported as having atypical squamous cells of undetermined origin (ASCUS), 10.1% were diagnosed as low grade squamous intraepithelial lesions (LSIL), 1.5 % had cells consistent with high grade squamous intraepithelial lesions (HSIL), and 0.001% were reported as cervical cancer. ASCUS and LSIL cases have traditionally been followed by colposcopy (cervical biopsy), an invasive, time-consuming, and costly procedure. For patients with ASCUS Pap results, the HPV test is useful to identify those patients with an increased risk that the atypical cells will progress to cervical cancer. A negative HPV test result indicates a low likelihood of disease progression, while patients with a positive HPV result should continue to be followed up with colposcopy.

Effective January 2008, SLPH has been performing HPV reflex testing on samples from women over the age of 20 with ASCUS Pap results, using the Hybrid Capture® 2 High-Risk HPV DNA Test® by Digene Corp. The assay, which detects thirteen high-risk HPV types, is not useful for testing in younger women since HPV infection in this age group is common and will usually clear on its own. Results so far show that approximately 60% of ASCUS patients test negative for high-risk HPV types, thereby reducing by over half the number of patients that would have previously been referred to colposcopy.

*Prepared by Myra Brinson, MT(ASCP),  
Virology/Serology Manager  
and Marjorie Lavender,  
Cancer Cytology Manager,  
NC State Laboratory of Public Health*

# New State Laboratory web site

The website for the North Carolina State Laboratory of Public Health has a new look! In an effort to better serve our clients and web visitors, the site has been completely revamped. Users will find new links added that will make useful information easier to find, including

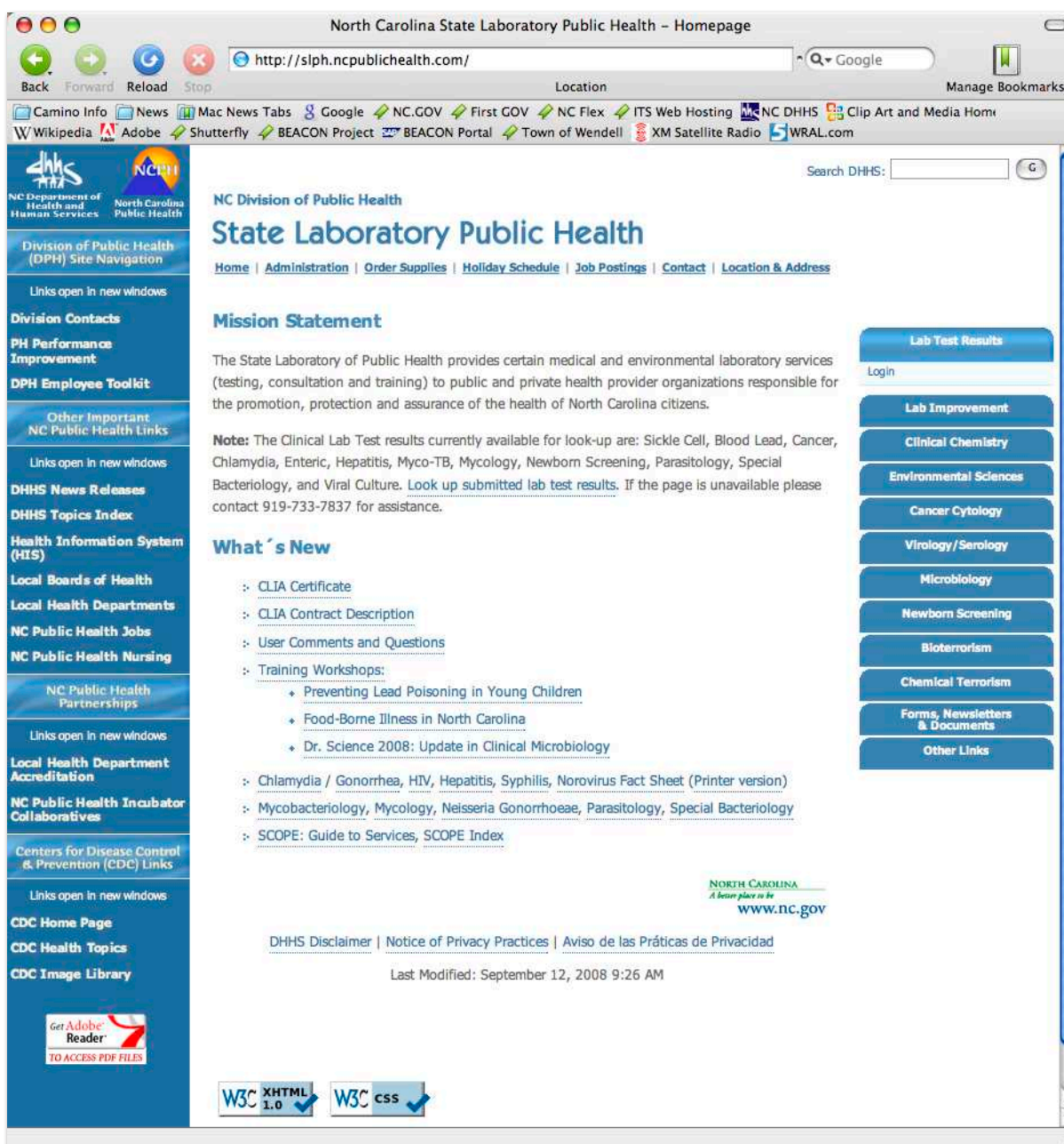
the state lab's CLIA certificate and the SCOPE Guide to Laboratory Services.

There are also links to jobs within the Division of Public Health, DHHS, CDC, and North Carolina Local Health Department Accreditation.

If you have questions or comments on the new site or laboratory operations, use the comments and questions link and let us know.

**Click on the following link and this is what you see:**

<http://slph.ncpublichealth.com>



# The Safety Corner

What's *Right* with This Picture?

“Emergency Shower and Eyewash Equipment”



When people work in a laboratory, accidents can happen. Engineering controls should be provided and maintained for the employees' protection. Two of the most valuable safety controls in the laboratory are eyewashes and safety showers. In the case of a blood spill or chemical splash, these devices may greatly reduce the extent of injury. However, they must be properly maintained so they remain in working order.

According to ANSI Z358.1, both eyewashes and safety showers must be flushed and checked weekly. This must be documented on a weekly log sheet. If the shower does not have a drain, shower kits can be purchased from many of the scientific vendors.

Showers and eyewashes must be easily accessible and never blocked. Mal-



functioning devices should be repaired immediately. Unused devices should be removed to avoid confusion during an emergency situation in which a patient or other health care professional may try to use them.

Noticeable signs should be used to clearly mark the equipment. Signage should be visible to all employees as well as to patients.

If you have any questions about this or any other safety issues, please contact Kristy Breedlove at [kristy.breedlove@ncmail.net](mailto:kristy.breedlove@ncmail.net) or (919) 733-7186. Look for the next installment of The Safety Corner when we will continue with the series, “What’s Right With This Picture”!

*Submitted by:*

*Kristy Breedlove, BS,*

*Laboratory Improvement Consultant,  
NCSLPH*

## “Dear Lab-bey...”

**If you have a technical laboratory question that you would like to have answered  
please submit it to: [Jennifer.A.Anderson@ncmail.net](mailto:Jennifer.A.Anderson@ncmail.net).**

**The answer to your question may be featured in the next edition of Lab-Oratory.**

**NCSLPH  
EYEWASH LOG - \_\_\_\_\_**

Lab: Laboratory ImprovementRoom Number: 402Tolerance Limits: 3 minute run time

Week	Date	Initial	Comment/Quarterly Supervisor Review	Week	Date	Initial	Comment/Quarterly Supervisor Review
1				27			
2				28			
3				29			
4				30			
5				31			
6				32			
7				33			
8				34			
9				35			
10				36			
11				37			
12				38			
13				39			
14				40			
15				41			
16				42			
17				43			
18				44			
19				45			
20				46			
21				47			
22				48			
23				49			
24				50			
25				51			
26				52			

**Instructions:**

1. Weekly, flush the eyewash nozzles with water by running for 3 minutes; the technologist should initial and date when performed.
2. Supervisory review: date and initial quarterly.

**Remedial actions:**

If problems are detected or procedure not performed, notify the supervisor and document on the reverse side.

## 2008 WORKSHOP SCHEDULE FOR OCTOBER-DECEMBER

# FALL

N.C. Department of Health and Human Services  
State Laboratory of Public Health  
**Laboratory Improvement (LI)**

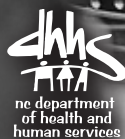
DATE	TITLE	APPLICATION DEADLINE DATE
October 8 & 9	Advanced Urinalysis	Sept. 10, 2008
October 14 & 15	Microscopy:Viewing & Reviewing (Basic)	Sept. 15, 2008
October 16	Diagnosing Vaginitis Using the Wet Mount Exam	Sept. 15, 2008
October 23	Waived Testing	Sept. 23, 2008
October 30	Bioterrorism Preparedness for Clinical Laboratories	Sept. 30, 2008
November 5	Microscopy:Viewing & Reviewing (Advanced)	Oct. 6, 2008
November 6	Diagnosing Vaginitis Using the Wet Mount Exam	Oct. 6, 2008
November 18-21	Bacteriological Methods for the Analysis of Drinking Water	Oct. 21, 2008
December 3 & 4	Laboratory Methods in the Diagnosis of Gonorrhea	November 4, 2008
December 5, 2008	Biosafety and Biosecurity: Minimizing the Risks in the Laboratory*	November 21, 2008

\*You can register for this class only at [register@aphl.org](mailto:register@aphl.org).

Disclaimer: These workshops are not intended to replace formal education  
but to enhance skills and promote use of recommended standard techniques.

For more information, consult your LI 2008 WORKSHOP ANNOUNCEMENTS or contact LI at 919-733-7186.

**<http://slph.state.nc.us>**



State of North Carolina | Department of Health and Human Services  
Division of Public Health | State Laboratory of Public Health  
[www.ncdhhs.gov](http://www.ncdhhs.gov)

N.C. DHHS is an equal opportunity employer and provider.  
09/08

# Kudos!

The NCSLPH continues to recognize exemplary employees by awarding the State Lab Employee of the Month. Employees are encouraged to nominate co-workers who demonstrate great work ethics and always lend a helping hand. Our latest recipients were:



**July** Zhong Zhang, Environmental Sciences  
**August** Shadia Barghothi, Microbiology  
**September** Kristy Breedlove, Laboratory Improvement

Congratulations to all of our winners and thank you for your contributions to the NCSLPH!

Wayne County Health Department deserves major Kudos! They are the first health department in North Carolina to receive the Public Sector Star award. This award is given through the NCDOL. This allows Wayne County the designation as "one of the safest workplaces". The award is given to those that demonstrate safety above and beyond the OSHA standards. It is based on our DART rates, recordable injury rates, number of employees, and lots of policies. The Public Sector Star is solely for state agencies and local governments. The award was approved on July 8, 2008, but an official ceremony will be held in the upcoming months. Congrats Wayne County Health Department!

Lab Improvement's Administrative Assistant, Cora Gibson deserves much praise. She just completed the Administrative Professional Certificate Program through the NC Office of State Personnel. She even received the "Early Bird Award"! Congrats Cora!

Please contact Kristy Breedlove at (919) 733-7186 or kristy.breedlove@ncmail.net if you would like to recognize a co-worker at your facility.

## EDITORIAL board

**Holly Lee**, Bioterrorism and Emerging Pathogens;  
**Patty Atwood**, NBS/CC;  
**Susie Lavender**, Cytology;  
**Brenda Webber**, Cytology;  
**Jennifer Anderson**, Lab Improvement;  
**Kristy Breedlove**, Lab Improvement;  
**Colleen Miller**, Lab Improvement;  
**Crystal Poppler**, Lab Improvement;  
**Janice West**, Lab Improvement;  
**Vanessa Campbell**, Virology/ Serology